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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,406	08/21/2001	George H. Lowell	40646-2000210	1965

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/938,406	LOWELL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zachariah Lucas	1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,4,6,9-17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4,6,9-17,19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8-16-05</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Currently, claims 3, 4, 6, 9-17, and 19-23 are pending in the application.
2. In the prior action, mailed on August 24, 2005, claims 1, 3, 4, 6-18 were under consideration and rejected.

In the Response of February 24, 2006, claims 3, 4, 6, 9-17 have been amended; claims 1, 7, 8, and 18 have been cancelled; and new claims 19-23 have been added. New claim 20 corresponds to previously withdrawn claim 2, and reads on non-elected subject matter. This claim is therefore withdrawn from consideration.

Claims 3, 4, 6, 9-17, 19, and 21-23 are under consideration.

#### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **(Prior Rejection- Withdrawn)** Claims 1, 3, 4, 6, 7, and 10-18 were rejected under 35 U.S.C. 103(a) as being obvious over the 292 patent (U.S. 5,726,291) in view of Anselem et al. (WO 94/26255). In view of the amendment of the claims requiring that the composition comprises an HIV antigen comprising residues 523-551 of SEQ ID NO: 1, the rejection is withdrawn.

5. **(Prior Rejection- Maintained)** Claims 1, 3, 4, 6, 7, 8, 10, 11, 16-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of the 292 patent or of Lowell (hereinafter, "the Lowell article," Science 240: 800-802), in view of Vancott, and further in view WO 95/11700. Claims 1, 7, 8, and 189 have been cancelled. The rejection is therefore withdrawn from these claims. However, new claims 19 and 21-23 have been added to the application. Claim 19 reads on the composition of cancelled claim 1, wherein the antigen is a C-terminally truncated gp160 protein comprising the endogenous sequence of residues 523-551 of SEQ ID NO: 1. Claims 21-23 rephrase the process limitations of claims 13-15. The rejection is therefore extended to new claims 19 and 21-23, and maintained against claims 3, 4, 6, 10, 11, 16, and 17.

The Applicant traverses this rejection on two grounds. First, the Applicant asserts that the cited combinations of references (either the 292 patent, Vancott, and WO 95/11700; or the Lowell article, Vancott, and WO 95/11700) do not teach or suggest compositions comprising a C-terminally truncated gp160 protein that includes that endogenous hydrophobic sequence of residues 523-551 of SEQ ID NO: 1. Second, the Applicant asserts that those in the art would have reasonably expected a C-terminally truncated gp160 protein to be able to form a complex with a proteosome- thereby indicating that the claimed invention would not have been obvious to those of ordinary skill in the art. Neither of these arguments is found persuasive.

With respect to the first argument in traversal, the teachings regarding the presence of a C-terminally truncated gp160 comprising residues 523-551 of SEQ ID NO: 1, it is noted that the present application teaches that such a truncated gp-160 is produced by a Clone 6D5 infected with the HTLV-III451 HIV strain. App., pages 21-22. Thus, the oligomeric gp160 antigen

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produced by such cells inherently meet this limitation. It is additionally noted that the Vancott reference teaches the use of a gp160 antigen produced as described by the Kalyanaraman et al. 1988 reference (cited as Kalyanaraman et al., AIDS Res Human Retrovir 4: 319). This reference teaches that the gp160 antigens described therein are produced from the same cells as are described on page 22 of the application. Thus, Vancott because Vancott suggests the use of HIV gp160 antigens from the same source, the reference inherently teaches the use of antigens having the structural features presently described.

With respect to the Applicant's second assertion, that those in the art would not have expected the antigens to be capable of forming complexes with proteosomes, this argument is not found persuasive because both the Lowell article and the 292 patent teach the attachment of lauroyl to antigens such that they will form a complex with the proteosome. See e.g., the Lowell article, abstract; and the 292 patent, abstract and column 4. Thus, recognition of the potential ability of the endogenous sequence of residues 523-551 of SEQ ID NO: 1 to enable the formation of this complex was not necessary for those of ordinary skill in the art to have a reasonable expectation of success in the combination.

For these reasons, and for the reasons of record, the Applicant's arguments in traversal are not found persuasive, and the rejection is maintained.

6. **(Prior Rejection- Maintained)** Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over the 292 patent or the Lowell article, in view WO 95/11700, and further in view of Vancott and Desai. The Applicant traverses this rejection for the same reasons as described above. These arguments are not found persuasive for the reasons described above.

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It is additionally noted that, with respect to claim 9, the teachings of Kalyanaraman (referred to by Vancott in the description of the antigens used to induce neutralizing antibodies) in comparison with those of pages 21-22 of the application as described above indicate that the Vancott reference does in fact specifically suggest the use of the antigen of claim 9. Thus, the additional teachings of Desai are redundant in part to the teachings of Vancott.

Thus, for the reasons above, and for the reasons of record, this rejection is maintained.

7. **(Prior Rejection- Withdrawn)** Claims 1, 6-13, 16-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings either of Anselem et al. (WO 94/26255) or of WO 95/11700 in view of the teachings of Vancott and Desai. The Applicant traverses this rejection for the same reasons as described above with respect to the rejections over either of the 292 patent or the Lowell article in view of WO 95/11700, and Vancott above. It is noted that, in contrast to the teachings of the 292 patent and the Lowell article, neither of the alternative primary references in this rejection teach the use of the lauroyl foot or anchor for the attachment of the antigen to a proteosome. Thus, the Applicant's arguments are found persuasive with respect to this rejection. The rejection is therefore withdrawn.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. **(Prior Rejection- Withdrawn)** Claims 1, 3, 4, 6, 7, 10-18 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7, and 8 of U.S. Patent No. 5,726,292. In view of the amendment of the claims as described above, the rejection is withdrawn.

10. **(Prior Rejection- Maintained)** Claims 1, 3, 4, 6-18 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7, and 8 of U.S. Patent No. 5,726,292 further in view of either of Anselem or WO 95/11700, and further in view of Vancott and Desai as described in the 103 rejection above. As described above, claims 17, 8, and 18 have been cancelled, and new claims 19 and 21-23 have been added.

The Applicant traverses this rejection on the same grounds as asserted with respect to the 103 rejection over the 292 patent, in view of Vancott, and further in view WO 95/11700, above. The rejection is therefore maintained over claims 3, 4, and 9-17, and extended to new claims 19 and 21-23, for the reasons indicated above.

### ***Conclusion***

11. No claims are allowed.

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12. The following prior art reference made of record and considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

Lowell, George, New Generation Vaccines pages 151-160. This reference is considered relevant to the present claims as, like the 292 patent and the Lowell article applied above, this reference also teaches the use of hydrophobic anchors to enable peptides and antigens to form complexes with proteosomes. See e.g., abstract.

U.S. 5,122,468. This reference provides similar teachings, with respect to the production of the HIV gp160 antigen, as provided in the Kalyanaraman reference, and on pages 21-22 of the present application as described above.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

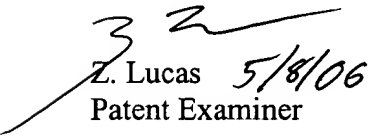
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Z. Lucas 5/8/06  
Patent Examiner



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